

PROTOCOL FOR SAFETY & FUNCTIONALITY TEST

The Sentec Digital Monitoring System (SDMS) has been designed to comply with the standards IEC 60601-1, ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1. For safety reasons it is recommended that the SDMS undergoes a technical safety check once a year (but the latest every two years) and after repair. Please fill in this form (one form per monitor).

Record the serial number and the hard- and software specific information of the tested items. You will find this information in the SDM menu "System information".

When using a Sentec Isolation Transformer, e.g. at a patient's home, the Isolation Transformer shall be tested according to IEC 62353 at least every six months.

THE SDMS SAFETY AND FUNCTIONALITY TEST CONSISTS OF SEVERAL TESTS OF THE FOLLOWING EQUIPMENT:

- Sentec TC Sensor (V-Sign™ Sensor 2 and/or OxiVenT™ Sensor)
- Sentec Digital Monitor
- SDM Docking Station
- Digital Monitor Extension Cable
- Sentec Isolation Transformer (if applicable)

This document must be filed until at least the next safety related test is performed.

TEST SUMMARY

Product Identification					
SDM	SN:		SW Version:	(SMB)	(MPB/MPL)
			HW Version:	(SMB)	(MPB/MPL)
Sensor	SN:		SW Version:		HW Version:
Test tools					
Multimeter:					
Safety analyser			Reference barometer:		
Sentec TC Sensor	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
Sentec Digital Monitor	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
SDM Docking Station	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
Digital Monitor Extension Cable	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
Sentec Isolation Transformer	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
Safety & Functionality test:	Not passed <input type="checkbox"/>		Passed* <input type="checkbox"/>		
Date of the next safety related test:					
Organization:				Location:	
Service technician (name):				Place, Date (YY-MM-DD:	
Signature:					

*all test items passed

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Completely fill in the tables below. Confirm that the tests have been performed successfully. If required, note test results. Confirm successfully passed tests with your signature or a check mark.

Sentec TC Sensor						
Test	Results			Passed		
Visual inspection				<input type="checkbox"/>		
Labeling				<input type="checkbox"/>		
Sensor LED (red)				<input type="checkbox"/>		
Sensor LED (green) (OxiVenT™ Sensor only)				<input type="checkbox"/>		
Sensor Temperature Display/Surveillance				<input type="checkbox"/>		
Cleaning / inspecting without membrane				<input type="checkbox"/>		
Sensitivity Test (PCO ₂ and/or PO ₂)				<input type="checkbox"/>		
Calibration Duration				<input type="checkbox"/>		
PCO ₂ Slope Test	Sensor SET temp.:	<input type="text"/>	° C (42°C)	<input type="checkbox"/>		
	Local P(atm):	<input type="text"/>				
	Measurement with 5 % CO₂					
	5_min:	<input type="text"/>	mmHg / kPa			
	5_max:	<input type="text"/>	mmHg / kPa			
	PCO ₂ (5%):	<input type="text"/>	mmHg / kPa			
PO ₂ Slope Test	Sensor SET temp.:	<input type="text"/>	° C (42°C)	<input type="checkbox"/>		
	Local P(atm):	<input type="text"/>				
	Measurement with 6 % O₂					
	6_min:	<input type="text"/>	mmHg / kPa			
	6_max:	<input type="text"/>	mmHg / kPa			
	PO ₂ (6%):	<input type="text"/>	mmHg / kPa			
Sensor Characteristic *	Measurement with 30 % CO₂			<input type="checkbox"/>		
	30_min:	<input type="text"/>	mmHg / kPa			
	30_max:	<input type="text"/>	mmHg / kPa			
	PCO ₂ (30%):	<input type="text"/>	mmHg / kPa			
	Measurement with 21 % O₂					
	21_min:	<input type="text"/>	mmHg / kPa			
21_max:	<input type="text"/>	mmHg / kPa				
PO ₂ (21%):	<input type="text"/>	mmHg / kPa	<input type="checkbox"/>			
Function test: PCO ₂	PCO ₂ :	<input type="text"/>	mV	<input type="text"/>	s	<input type="checkbox"/>
Function test: PO ₂	PO ₂ only:	<input type="text"/>	mmHg	<input type="text"/>	s	
Function test: SpO ₂ + PR	Value:	<input type="text"/>	%	<input type="text"/>	bpm	<input type="checkbox"/>
	Reference:	<input type="text"/>	%	<input type="text"/>	bpm	<input type="checkbox"/>

* Go to SDM menu "System information" and press the "enter" button to obtain this information.

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Sentec Digital Monitor					
Test	Results			Passed	
Visual inspection				<input type="checkbox"/>	
Labeling				<input type="checkbox"/>	
Safety test IEC 60601-1 / IEC 62353 according to SDMS Service Manual (HB-005615)	Test performed according to IEC 60601-1 <input type="checkbox"/> IEC 62353 <input type="checkbox"/>			<input type="checkbox"/> <input type="checkbox"/>	
POST				<input type="checkbox"/>	
Keyboard				<input type="checkbox"/>	
Clock settings				<input type="checkbox"/>	
Display / LEDs				<input type="checkbox"/>	
Speaker (POST)				<input type="checkbox"/>	
Fan				<input type="checkbox"/>	
Barometric pressure				<input type="checkbox"/>	
Analog output				<input type="checkbox"/>	
Serial data port (RS-232)				<input type="checkbox"/>	
LAN test 1 (V-CareNeT™: green connection status icon)				<input type="checkbox"/>	
LAN test 2 (V-CareNeT™: time and serial number)				<input type="checkbox"/>	
Rechargeable Lithium Battery capacity	Runtime until shut down:		h	min	<input type="checkbox"/>
Display, alarm				<input type="checkbox"/>	
Speaker, alarm				<input type="checkbox"/>	
Nurse Call, alarm				<input type="checkbox"/>	
AC power cord, visual and safety test				<input type="checkbox"/>	

* If no value is displayed, enter "N.A." or leave blank.

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SDM Docking Station		
Test	Results	Passed
Visual inspection		<input type="checkbox"/>
Gas indicator		<input type="checkbox"/>
Docking Station Gasket replaced		<input type="checkbox"/>

Digital Monitor Extension Cable		
Visual inspection		<input type="checkbox"/>

Gas Bottle			
Gas Bottle Expiry Date	Date (YY-MM-DD):		<input type="checkbox"/>

Sentec Isolation Transformer		
Test	Results	Passed
Visual inspection IEC 62353		<input type="checkbox"/>
Labeling		<input type="checkbox"/>
Electrical/functional test IEC 62353		<input type="checkbox"/>
AC power cord, visual and safety test		<input type="checkbox"/>